"composition". Support for the amendment of claim 1 is found throughout the specification, specifically at page 4 of the specification, especially lines 2-8. New claims 10-36 are directed to additional aspects of the claimed invention and each depend from claim 1. The various types of permeation control layers of claims 10-13 are described at page 4 of the specification and the various types of medicine storage layers of claims 14-31 are described at page 5, third full paragraph, of the specification. The compositions of claims 32-34 are described at page 5, first full paragraph, and page 6, first paragraph, of the specification. The methods of claims 35 and 36 are described at pages 6-8 of the specification and exemplified in the Examples on pages 8-14. Accordingly, the Applicants do not believe that any new matter has been added.

Information Disclosure/Documents Cited on the International Search Report

The Applicants thank Examiner Sheikh for acknowledging the documents cited in the International Search Report as set forth on Form 1449.

Rejection -- 35 U.S.C. 102

Claims 1-9 were rejected under 35 U.S.C. 102(b) as being anticipated by Pfister et al., U.S. Patent 5,232,702. Applicants submit that this rejection may now be withdrawn in view of the amendment of claim 1 to further clarify that the recited permeation control film and medicine storage layer differs from the "rate controlling membrane" and "liquid reservoir"of Pfister.

As discussed in the interview, Pfister describes matrix and reservoir type devices. As shown in Fig. 2, the matrix device of Pfister does not contain the permeation control film of

the present invention, only a backing (22), matrix (24) containing a drug (26) and a release liner (28).

As shown in Fig. 3, the liquid reservoir device of Pfister contains a liquid reservoir (30) instead of the present invention's medicine storage layer comprising one or more medicine(s) that permeate, dissolve, disperse or diffuse into a plasticized permeation control film once it has been activated by moisture.

Fig. 4 of Pfister shows a solid reservoir system that may optionally contain a "rate controlling membrane", see col. 9, lines 15-16. However, this term appears to be merely functional, as there is no material description of what a rate controlling membrane is. A cited reference must be enabling in order to anticipate, see MPEP 2121.01. Pfister does not provide a material description of a rate controlling membrane and his examples do not refer to rate controlling membranes. Therefore, the Applicants submit that Pfister is non-enabling with respect to "rate controlling membranes" and would not anticipate the permeation control film of the present invention.

Moreover, even if Pfister were enabling and the permeation control film of the present invention were deemed to be one type of a rate controlling membrane, Pfister does not disclose a permeation controlling film that is plasticized when activated by moisture from the skin and that permits the permeation of the medicine(s) out of the medicine storage layer when plasticized. Therefore, Pfister also fails to teach all the elements of the present invention and cannot anticipate the permeation control film of claim 1 as amended. Additionally, Pfister does not describe the particular materials recited by the new dependent claims 10-13.

Similarly, the present invention is not obvious over the cited art because there is no suggestion in Pfister make a device comprising a permeation controlling film that once

moistened by the skin allows a medicine to permeate and pass through the layer to the skin. Accordingly, the Applicants respectfully submit that this rejection may now be withdrawn.

Rejection -- 35 U.S.C. 103

Claims 7 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pfister et al., U.S. Patent 5,232,702 by itself, or in view of Hodgeson, U.S. Patent 3,645,835. Applicants submit that this rejection may be withdrawn in view of the comments above distinguishing Pfister from the present invention. Hodgeson is directed to moisture-vapor permeable adhesive materials and does not disclose the permeation controlling film and medicine storage layer of the present invention. As discussed, this document was cited to disclose moisture-vapor-permeability of at least 300 g/m^2. As Pfister et al. do not suggest the claimed invention for the reasons discussed above, nor does Hodgeson disclose or suggest the present invention, the Applicants respectfully request that this rejection now be withdrawn.

Conclusion

In view of the above amendments and remarks, the Applicants respectfully submit that claims 1-36 are now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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IN THE CLAIMS

Please amend Claims 1-9 as follows:

--1. (Amended) A [percutaneous absorption preparation] composition comprising:

a supporting body,

a medicine storage layer comprising one or more medicine(s) that permeate, dissolve, disperse or diffuse into a plasticized permeation control film which has been activated by moisture,

a permeation controlling film that is plasticized when activated by moisture from the skin and that permits the permeation of the medicine(s) out of the medicine storage layer when plasticized,

a layer of an adhesive and

a release liner,

[which is characterized in that said permeation controlling film is plasticized by moisture volatilized from the skin at the time of application of the preparation].

2. (Amended) [A percutaneous absorption preparation] The composition according to [C]claim 1[, wherein said] comprising a permeation controlling film that is a water-soluble polymer.

3. (Amended) [A percutaneous absorption preparation] The composition according to [C]claim 1 [2, wherein said water-soluble polymer is] comprising a permeation controlling film that is poly(vinyl alcohol).

4. (Amended) [A percutaneous absorption preparation] The composition according to [C]claim 1[, wherein said] comprising a medicine storage layer that is formed by a medicine, or by a medicine and a vehicle.

5. (Amended) [A percutaneous absorption preparation] The composition according to [C]claim 4[, wherein said] that comprises a medicine that is water-soluble.

6. (Amended) [A percutaneous absorption preparation] The composition according to [C]claim 4[, wherein said] that comprises a vehicle that is a water-disintegrative substance.

7. (Amended) [A percutaneous absorption preparation] The composition according to [C]claim 1[, wherein said] comprising a supporting body that has a water-vapor permeability of 100 g/m^2 or less at the condition of 40° C and 24 hours.

8. (Amended) [A percutaneous absorption preparation] The composition according to [C]claim 1[, wherein said] that comprises an adhesive that has a water-vapor permeability of 100g/m^2 or more at the condition of 40° C and 24 hours.

9. (Amended) [A percutaneous absorption preparation] The composition according to [C]claim 1[, wherein the therapeutic] that comprises a medicine that is nicorandil, dopamine hydrochloride or eperisone hydrochloride.

Claims 10-36 (New).--